

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION**

SARAH BENTON,

Plaintiff,

v.

**PFIZER, INC., PHARMACIA
CORPORATION, G.D. SEARLE LLC,
(FKA G.D. SEARLE & CO.), and
MONSANTO COMPANY,**

Defendants.

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CIVIL CASE # _____

COMPLAINT

COMES NOW, Sarah Benton ("Plaintiff"), complaining of Pfizer, Inc., Pharmacia Corporation, G.D. Searle LLC (fka G.D. Searle & Co.), and Monsanto Company ("Defendants"), and for her cause of action against the Defendants states as follows:

Statement of the Parties

1. This is a Civil Action brought on behalf of Plaintiff, Sarah Benton. Plaintiff is a resident of Douglas County, Georgia. Pursuant to Minn. Stat. section 303.02(6) (1990), a Plaintiff who is a non-resident of Minnesota is able to bring action in this Court against foreign corporation Defendants. This Court has jurisdiction over this case under section 303.02(6), because Defendants conducted business in the State of Minnesota through pharmaceutical sales representatives conducting business in the State of Minnesota on behalf of Defendants, thus there exists a sufficient nexus between the Defendants' forum contacts and the Plaintiff's cause of action to justify assertion of jurisdiction in Minnesota.

2. Defendant PFIZER, INC. ("PFIZER") is a Delaware corporation with its principal place of business in New York, New York. On July 16, 2002 PFIZER announced its proposed

acquisition of PHARMACIA CORPORATION (“PHARMACIA”). On April 16, 2003, PFIZER completed its \$60 billion acquisition of PHARMACIA. As a wholly-owned subsidiary of PFIZER, PHARMACIA acted in all aspects as PFIZER’s agent and alter ego. At all relevant times, PFIZER and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecosib, under the trade name BEXTRA in Minnesota and throughout the United States. Defendant PFIZER is licensed and registered to do business in the State of Minnesota and may be served through its registered agent at Pfizer, Inc., 405 2nd Avenue South, Minneapolis, Minnesota 55401.

3. Defendant G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.) (“SEARLE”) is a Delaware corporation with its principal place of business in Illinois. In April 2000 SEARLE was acquired by PHARMACIA, and became a wholly-owned subsidiary of PHARMACIA. At the time of PFIZER’s acquisition of PHARMACIA, SEARLE was a wholly-owned subsidiary of PHARMACIA, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER. At all relevant times, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecosib, under the trade name BEXTRA in Minnesota and throughout the United States. G.D. Searle LLC’s principal place of business is in Illinois and may be served through its registered agent at C T Corporation System, 208 South LaSalle Street, Suite 814, Chicago, Illinois 60604.

4. Defendant PHARMACIA is a Delaware corporation with its principal place of business in New Jersey. PHARMACIA was created in April 2000 through the merger of Pharmacia & Upjohn with Monsanto Company and its G.D. SEARLE unit. PHARMACIA is

now a wholly-owned subsidiary of PFIZER. At all relevant times, PHARMACIA, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecxib, under the trade name BEXTRA in Minnesota and throughout the United States. Pharmacia's principal place of business is in Illinois and may be served at its principal place of business at 100 U. S. Highway 206 North, Peapack, New Jersey 07977.

5. Defendant MONSANTO COMPANY ("MONSANTO") was the parent corporation of SEARLE and is a Delaware corporation. At all times relevant hereto, MONSANTO, through its subsidiary companies, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product BEXTRA in Minnesota and throughout the United States. Defendant MONSANTO is licensed and registered to do business in the State of Minnesota and may be served through its registered agent at Monsanto Company, 380 Jackson Street #418, St. Paul, Minnesota 55101.

6. Valdecxib was developed in 1998 by SEARLE and marketed jointly by SEARLE and PFIZER under the brand name BEXTRA. SEARLE was acquired by PHARMACIA, which was then acquired by PFIZER, in part so that PFIZER could take full control of BEXTRA.

7. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of BEXTRA, and advertised, promoted, marketed, sold and distributed BEXTRA as a safe prescription medication when, in fact, Defendants had reason to know, and did know, that BEXTRA was not safe for its intended purposes, for the patients for whom it was prescribed,

and for whom it was sold; and that BEXTRA caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

8. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants, or those Defendant's predecessors in interest.

9. Personal jurisdiction and subject matter jurisdiction are appropriate in this court as to all Defendants, as all Defendants have done business in Hennepin County, Minnesota, either directly or by agent, and have thus availed themselves of this jurisdiction.

10. The Defendants have been and/or are currently engaged in business, directly or by authorized agent, in Hennepin County, Minnesota. Venue and jurisdiction are therefore proper. The claims of the Plaintiff herein satisfy the jurisdictional amount of this Court.

Factual Background

A. Facts Regarding Plaintiff

11. Plaintiff was prescribed and began taking BEXTRA for the treatment of pain.

12. As a direct and proximate result of using BEXTRA, Plaintiff suffered a heart attack on or around July 11, 2004.

13. Plaintiff and Plaintiff's healthcare providers were at the time of Plaintiff's injuries unaware—and could not have reasonably known or have learned through reasonable diligence—that such injury directly resulted from Plaintiff's ingestion of BEXTRA and Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations.

14. Plaintiff used BEXTRA in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

15. Plaintiff would not have purchased and used BEXTRA had Defendants properly disclosed the risks associated with the drug, and through diligent effort was not able to discover the risk from BEXTRA prior to use of the drug.

A. Facts Regarding Bextra and Bextra's Market Launch

16. BEXTRA is one of a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil) are examples of well-known NSAIDs.

17. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

18. In addition to decreasing inflammation, the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

19. Prostaglandin I2 is the predominant cyclooxygenase product in endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation, and preventing the proliferation of vascular smooth muscle. Whereas older NSAIDs inhibit Thromboxane A2 and Prostaglandin I2, the COX-2 inhibitors leave Thromboxane A2 unaffected. Thromboxane A2 is a potent platelet aggregator and vasoconstrictor, which is synthesized by platelets. Therefore, while the older NSAIDs suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors support it.

20. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood clots, rather they actually reduce the risk of clots and help protect heart function.

21. Defendants and other pharmaceutical companies set out to remedy these ulcer and bleeding problems suffered by some NSAID users by developing "selective" inhibitors that

would block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue while still reducing inflammation.

22. In making this decision, Defendants and their predecessors in interest either intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels and causes thromboxane A₂ to be uninhibited, causing blood clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke, unstable angina. The vasoconstriction and fluid retention cause the hypertension.

23. Pfizer launched Celebrex, the first of the three major COX-2 inhibitor drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and consumers of the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In May 1999, Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.

24. Seeking increased market share in this extremely lucrative market, Defendants, and their predecessors in interest, also sought approval of a “second generation” selective COX-2 inhibitor and filed for FDA approval of BEXTRA on January 16, 2001 for the (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

25. The FDA granted approval of the new drug on November 16, 2001, for two particular uses: (i) treatment of primary dysmenorrhea and (ii) relief for the signs and symptoms of osteoarthritis and rheumatoid arthritis.

26. The FDA did not grant approval to market and promote BEXTRA for the management or prevention of acute pain.

27. The FDA did not grant approval to promote BEXTRA as more effective than other NSAIDs in preventing clinically serious gastrointestinal events such as perforations, ulcers or gastric bleeding.

28. Even without a label that allowed Defendants to legitimately claim superior safety, when Defendants, and their predecessors-in-interest, began marketing BEXTRA in early 2002, Defendants and their representatives and agents misrepresented the safety profile of

BEXTRA to consumers, including Plaintiff, the medical community, healthcare providers, and third party payers. Defendants proceeded to promote, market, sell, and distribute BEXTRA as a much safer and more effective pain reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

B. Facts Regarding Bextra's Safety and Defendants' Knowledge Thereof.

29. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Defendants long before the FDA granted market approval in November 2, 2001. By 1997, and prior to the submission of the New Drug Application (the "NDA") for BEXTRA, Defendants was aware that, by inhibiting COX-2, BEXTRA altered the homeostatic balance between prostacyclin synthesis and thromboxane and thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, *Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, *JAMA*, August 22, 2001 at 954. Although all COX-2 inhibitors have this mechanism of action, BEXTRA was the most selective COX-2 inhibitor proposed for approval. Accordingly, it had the greatest potential to cause adverse cardiovascular and cerebrovascular events.

30. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania, reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that it was known as early as 1999 that selective COX-2 inhibitors, such as BEXTRA, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.

31. Nevertheless, on January 16, 2001, Defendants submitted an NDA to the FDA for BEXTRA, omitting information about the extent of the risks associated with BEXTRA. Without a complete picture of the potential hazards associated with the drug, the FDA approved BEXTRA on or about November 16, 2001.

32. Based on the studies performed on Celebrex, Vioxx, BEXTRA, and other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, Defendants knew when BEXTRA was being developed and tested that selective

COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors. Studies show that selective COX-2 inhibitors, including BEXTRA, decrease blood levels of a prostacyclin. When those levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

33. On December 9, 2004, the FDA issued new information on side effects associated with the use of BEXTRA and required the addition of certain warnings to, and the strengthening of other warnings on, the BEXTRA label. The enhanced warnings followed in the wake of the results of additional cardiovascular studies performed by Defendants, as well as numerous complaints to the FDA regarding severe skin reactions.

34. Yet well prior to this warning, Defendants had knowledge of the coronary and cardiovascular safety risks of BEXTRA from several studies. *See e.g., Otto, E.O., Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing Coronary Artery Bypass Surgery, The Journal of Thoracic and Cardiovascular Surgery*, June 2003 at 1481.

35. Even Defendants' own (and Pfizer funded) post- drug approval meta-analysis study (first presented on March 31, 2003 and again on May 15, 2003) included this data showing an increased cardiovascular risk in patients treated with BEXTRA after undergoing coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood clots in the legs and lungs. The results were particularly relevant and striking as each of the study participants who were a post-bypass surgery patient was taking anti-clotting agents at the time their exposure to BEXTRA was being tracked.

36. In mid-January 2005, a peer-reviewed paper from the University of Pennsylvania found that in patients having heart bypass surgery, those who took BEXTRA in the intravenous form, parecoxib, as opposed to a placebo, were three times more likely to have a heart attack or stroke.

37. From February 16-18, 2005, the FDA's Drug Safety and Risk Management Advisory Committee and the Arthritis Drug Advisory Committee met jointly to further examine the safety of COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham testified that selective COX-2 inhibitors increase the risk for adverse cardiovascular events at about the same rate as cigarette smoking, hypertension, and diabetes.

38. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of BEXTRA, Defendants failed to take any action to protect the health and welfare of patients, but instead, continued to promote the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

39. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily withdraw" BEXTRA from the U.S. market, stating:

"... the Agency has concluded that the overall risk versus benefit profile of BEXTRA is unfavorable. This conclusion is based on the potential increased risk for serious cardiovascular (CV) adverse events, which appears to be a class effect of non-steroidal anti-inflammatory drugs (NSAIDs) (excluding aspirin), an increased risk of serious skin reactions (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other NSAIDs, and the fact that BEXTRA has not been shown to offer any unique advantage over the other available NSAIDs."

40. FDA Alert for Healthcare Professionals, April 7, 2005. Continuing, the FDA noted:

"BEXTRA has been demonstrated to be associated with an increased risk of serious adverse CV events in two short-term trials in patients immediately post-operative from coronary artery bypass graft (CABG) surgery FDA has concluded that it is reasonable to extrapolate the adverse CV risk information for BEXTRA from the short-term CABG trials to chronic use given the fact that other COX-2 selective NSAIDs have been shown in long-term controlled clinical trials to be associated with an increased risk of serious adverse CV events (e.g., death, MI, stroke), and the well described risk of serious, and often life-threatening gastrointestinal bleeding To date, there have been no studies that demonstrate an advantage of BEXTRA over other

NSAIDs that might offset the concern about the[] serous skin risks, such as studies that show a GI safety benefit, better efficacy compared to other products, or efficacy in a setting of patients who are refractory to treatment with other products.”

41. The scientific data available during and after BEXTRA’s approval process made clear to Defendants that their formulation of BEXTRA would cause a higher risk of blood clots, stroke and/or myocardial infarctions among BEXTRA consumers, alerting them to the need to do additional and adequate safety studies.

42. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining Defendants’ failure to have conducted the necessary trials before marketing to humans “... it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events.”

43. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

44. Based upon readily available scientific data, Defendants knew, or should have known, that their pre-approval testing of BEXTRA did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take BEXTRA. Therefore, Defendants’ testing and studies were grossly inadequate. *See, e.g.*, PDR entry for BEXTRA (noting that: “**Platelets:** In four clinical studies with young and elderly (>=65 years) subjects, single and multiple doses up to 7 day mg BID had no effect on platelet aggregation”).

45. Had Defendants done adequate testing prior to approval and “market launch,” rather than the extremely short duration studies done on the small size patient base that was actually done) Pharmacia and Searle’s scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of BEXTRA consumers. Adequate testing would have shown that BEXTRA possessed serious side effects for individuals such as Plaintiff. Defendants should have taken appropriate measures to

ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

46. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but this information was intentionally suppressed by Defendants in order for them to gain significant profits from continued BEXTRA sales.

47. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

48. At the time Defendants manufactured, advertised, and distributed BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers such as Plaintiff would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAIDs.

C. Facts Regarding Defendants' Marketing and Sale of Bextra

49. Plaintiff and at all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers would perceive BEXTRA as a safer and better drug than its other NSAIDs and, therefore, purchase BEXTRA.

50. Defendants widely and successfully marketed BEXTRA throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff's prescribing physicians.

51. Despite knowledge of the dangers presented by BEXTRA, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for

the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, BEXTRA, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

52. In an elaborate and sophisticated manner, Defendants aggressively marketed BEXTRA directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payers, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include BEXTRA on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from Defendants' successful advertising and marketing blitz, third party payers were compelled to add BEXTRA to their formularies. Defendants' marketing campaign specifically targeted third party payers, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of BEXTRA.

53. Defendants represented that BEXTRA was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance, NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with long-term use. Defendants promoted BEXTRA as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

54. BEXTRA possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable

angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition, BEXTRA was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Defendants chose not to warn about these risks and dangers.

55. Defendants knew of these risks before the U.S. Food and Drug Administration (the “FDA”) approved BEXTRA for sale on November 16, 2001, but Defendants ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of BEXTRA. Defendants’ omission, suppression, and concealment of this important information enabled BEXTRA to be sold to, and purchased, or paid for by, the Consumers at a grossly inflated price.

56. Consequently, BEXTRA captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2002 alone (after a drug launch in March of 2002), sales of BEXTRA exceeded \$1.5 billion, despite the significantly higher cost of BEXTRA as compared to other pain relievers in the same family of drugs.

57. It was not until April 7, 2005, that Defendants finally acknowledged BEXTRA’s deleterious side effects and announced that they were withdrawing the drug from the worldwide market based on what it misleadingly termed “new” and “unexpected” evidence linking BEXTRA to an increased risk of heart attacks and strokes.

58. Had Defendants done adequate testing prior to approval and “market launch,” Pharmacia’s scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of BEXTRA consumers. Adequate testing would have shown that BEXTRA possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

59. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but this information was intentionally suppressed by Defendants in order for them to gain significant profits from continued BEXTRA sales.

60. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

61. At the time Defendants manufactured, advertising, and distributed BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers such as plaintiff would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAID drugs.

62. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers, including plaintiff, and their doctors would perceive BEXTRA as a better drug than its competitors and, therefore, purchase BEXTRA.

63. Defendants widely and successfully marketed BEXTRA throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff's prescribing physicians.

64. Prior to manufacturing, sale and distribution of BEXTRA, Defendants, through their officers, director and managing agents, had notice and knowledge from several sources, that BEXTRA presented substantial and unreasonable risks of harm to the consumer. As such, BEXTRA consumers, including Plaintiff, were unreasonably subject to risk of injury or death from the consumption of Defendants' product, BEXTRA.

65. Despite such knowledge, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, BEXTRA, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants and their officers, agents and managers intentionally proceeded with the inadequate testing, and then the manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence

66. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

67. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling BEXTRA. This duty included the duty not to introduce a pharmaceutical drug, such as BEXTRA, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

68. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiff and the Public of the risks, dangers and adverse side effects of their pharmaceutical drug BEXTRA.

69. Defendants breached their duties by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of BEXTRA, including:

(a) failing to use due care in the preparation and development of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

- (b) failing to use due care in the design of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- (c) failing to conduct adequate pre-clinical testing and research to determine the safety of BEXTRA;
- (d) failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of BEXTRA;
- (e) failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA;
- (f) failing to accompany BEXTRA with proper warnings regarding all possible adverse side effects associated with the use of BEXTRA;
- (g) failing to use due care in the manufacture, inspection, and labeling of BEXTRA to prevent the aforementioned risk of injuries to individuals who used BEXTRA;
- (h) failing to use due care in the promotion of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- (i) failing to use due care in the sale and marketing of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- (j) failing to use due care in the selling of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- (k) failing to provide adequate and accurate training and information to the sales representatives who sold BEXTRA;
- (l) failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of BEXTRA; and
- (m) being otherwise reckless, careless and/or negligent.

70. Despite the fact that Defendants knew or should have known that BEXTRA caused unreasonable and dangerous side effects which many users would be unable to remedy by

any means, Defendants continued to promote and market BEXTRA to consumers, including Plaintiff, when safer and more effective methods of pain relief were available.

71. Defendants were, or should have been had they exercised reasonable care, in possession of evidence demonstrating that BEXTRA caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of BEXTRA.

72. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described above.

73. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

74. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SECOND CLAIM FOR RELIEF
Strict Liability

75. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleged as follows:

76. At all times relevant to this action, Defendants were suppliers of BEXTRA, placing the drug into the stream of commerce. BEXTRA was expected to and did reach Plaintiff without substantial change in the condition in which it was manufactured and sold.

77. BEXTRA was unsafe for normal or reasonably anticipated use.

78. BEXTRA was defective in design or formulation because when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect. BEXTRA was also defective and unreasonably dangerous in that the foreseeable risk of injuries from BEXTRA exceeded the benefits associated with the design and/or formulation of the product.

79. BEXTRA is unreasonably dangerous: (a) in construction or composition; (b) in design; (c) because an adequate warning about the product was not provided; (d) because it does not conform to an express warranty of the manufacturer about the product.

80. BEXTRA as manufactured and supplied by Defendants was also defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study. Defendants failed to perform adequate testing before exposing Plaintiff to the medication, testing which would have shown that BEXTRA had the potential to cause serious side effects including the injuries suffered like the Plaintiff.

81. BEXTRA as manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from BEXTRA, they failed to provide adequate warnings to the medical community and the consumers, to whom they were directly marketing and

advertising BEXTRA; and, further, it continued to affirmatively promote BEXTRA as safe and effective.

82. BEXTRA was manufactured, distributed, tested, sold, marketed, advertised and promoted defectively by Defendants, and as a direct and proximate cause of Defendants' defective design of BEXTRA, Plaintiff used BEXTRA rather than other safer and cheaper NSAIDs. As a result, Plaintiff suffered the personal injuries described herein.

83. Information given by Defendants to the medical community and to the consumers concerning the safety and efficacy of BEXTRA, especially the information contained in the advertising and promotional materials, did not accurately reflect the potential side effects of BEXTRA.

84. Had adequate warnings and instructions been provided, Plaintiff would not have taken BEXTRA, and would not have been at risk of the harmful side effects described herein.

85. Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by BEXTRA.

86. Plaintiff could not, through the exercise of reasonable care, have discovered BEXTRA's defects or perceived the dangers posed by the drug.

87. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

88. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers,

including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

89. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF
Breach of Express Warranty

90. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

91. Defendants expressly represented to Plaintiff and other consumers and the medical community that BEXTRA was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

92. These warranties came in the form of:

- (a) Defendants' public written and verbal assurances of the safety and efficacy of BEXTRA;
- (b) Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for BEXTRA, which failed to warn of the risk of injuries inherent to the ingestion of BEXTRA, especially to the long-term ingestion of BEXTRA;
- (c) Verbal and written assurances made by Defendants regarding BEXTRA and downplaying the risk of injuries associated with the drug;
- (d) False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing BEXTRA during the period of Plaintiff's ingestion of BEXTRA, and;

(e) advertisements.

93. The documents referred to above were created by and at the direction of Defendants.

94. Defendants knew or had reason to know that BEXTRA did not conform to these express representations in that BEXTRA is neither as safe nor as effective as represented, and that BEXTRA produces serious adverse side effects.

95. BEXTRA did not and does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

96. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

97. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

98. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

99. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FOURTH CLAIM FOR RELIEF
Breach of Implied Warranty

100. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

101. Defendants manufactured, distributed, advertised, promoted, and sold BEXTRA.

102. At all relevant times, Defendants knew of the use for which BEXTRA was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

103. BEXTRA was not of merchantable quality and was not fit for its intended use, because it causes increased risk of serious cardiovascular and cerebrovascular adverse events, including heart attacks, strokes and other serious and harmful adverse health effects, such as death.

104. Defendants breached the implied warranty that BEXTRA was of merchantable quality and fit for such use.

105. Defendants were aware that consumers, including Plaintiff, would use BEXTRA for treatment of pain and inflammation and for other purposes.

106. Plaintiff and the medical community reasonably relied upon Defendants' judgment and expertise to only sell them or allow them to prescribe BEXTRA only if it was indeed of merchantable quality and safe and fit for its intended use. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for BEXTRA.

107. BEXTRA reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

108. Defendants breached their implied warranty to consumers, including Plaintiff; BEXTRA was not of merchantable quality or safe and fit for its intended use.

109. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

110. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

111. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF
Fraudulent Misrepresentation & Concealment

112. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

113. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers

of BEXTRA, and their intentional dissemination of promotional and marketing information about BEXTRA for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about BEXTRA's risks and harms to doctors and consumers.

114. Defendants made fraudulent affirmative misrepresentations with respect to BEXTRA in the following particulars:

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that BEXTRA had been tested and found to be safe and effective for the treatment of pain and inflammation; and

(b) Defendants represented that BEXTRA was safer than other alternative medications.

115. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of BEXTRA.

116. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that BEXTRA had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiff.

117. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of BEXTRA including, but not limited to, the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of BEXTRA in order to increase its sales.

118. The representations and concealment were undertaken by Defendants with an intent that doctors and patients, including Plaintiff, rely upon them.

119. Defendants' representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of BEXTRA.

120. Defendants' fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

121. Plaintiff's physicians and Plaintiff relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of BEXTRA in selecting BEXTRA treatment.

122. Plaintiff and the treating medical community did not know that the representations were false and were justified in relying upon Defendants' representations.

123. Had Plaintiff been aware of the increased risk of side effects associated with BEXTRA and the relative efficacy of BEXTRA compared with other readily available medications, Plaintiff would not have taken BEXTRA as she did.

124. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

125. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

126. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTH CLAIM FOR RELIEF
(Unjust Enrichment)

127. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein.

128. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of BEXTRA.

129. Plaintiff paid for BEXTRA for the purpose of managing her pain safely and effectively.

130. Defendants have accepted payment from Plaintiff for the purchase of BEXTRA.

131. Plaintiff did not receive the safe and effective pharmaceutical product for which she paid.

132. It is inequitable and unjust for Defendants to retain this money because the Plaintiff did not in fact receive the product Defendant represented BEXTRA to be.

133. WHEREFORE, Plaintiff demands judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

1. General damages in excess of the jurisdictional amount of this Court;

2. Consequential damages;
3. Disgorgement of profits;
4. Restitution;
5. Punitive and exemplary damages;
6. Pre-judgment and post-judgment interest as provided by law;
7. Recovery of Plaintiff's costs including, but not limited to, discretionary


Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and

8. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

COMES NOW Plaintiff and demands a trial by jury on all issues presented herein.

Signed this 1 day of April, 2008.



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ATTORNEYS FOR PLAINTIFF

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION

SARAH BENTON,

Plaintiff,

v.

PFIZER, INC., PHARMACIA
CORPORATION, G.D. SEARLE LLC,
(FKA G.D. SEARLE & CO.), and
MONSANTO COMPANY,

Defendants.

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CIVIL CASE # _____

COMPLAINT

COMES NOW, Sarah Benton (“Plaintiff”), complaining of Pfizer, Inc., Pharmacia Corporation, G.D. Searle LLC (fka G.D. Searle & Co.), and Monsanto Company (“Defendants”), and for her cause of action against the Defendants states as follows:

Statement of the Parties

1. This is a Civil Action brought on behalf of Plaintiff, Sarah Benton. Plaintiff is a resident of Douglas County, Georgia. Pursuant to Minn. Stat. section 303.02(6) (1990), a Plaintiff who is a non-resident of Minnesota is able to bring action in this Court against foreign corporation Defendants. This Court has jurisdiction over this case under section 303.02(6), because Defendants conducted business in the State of Minnesota through pharmaceutical sales representatives conducting business in the State of Minnesota on behalf of Defendants, thus there exists a sufficient nexus between the Defendants’ forum contacts and the Plaintiff’s cause of action to justify assertion of jurisdiction in Minnesota.

2. Defendant PFIZER, INC. (“PFIZER”) is a Delaware corporation with its principal place of business in New York, New York. On July 16, 2002 PFIZER announced its proposed

acquisition of PHARMACIA CORPORATION (“PHARMACIA”). On April 16, 2003, PFIZER completed its \$60 billion acquisition of PHARMACIA. As a wholly-owned subsidiary of PFIZER, PHARMACIA acted in all aspects as PFIZER’s agent and alter ego. At all relevant times, PFIZER and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecoxib, under the trade name BEXTRA in Minnesota and throughout the United States. Defendant PFIZER is licensed and registered to do business in the State of Minnesota and may be served through its registered agent at Pfizer, Inc., 405 2nd Avenue South, Minneapolis, Minnesota 55401.

3. Defendant G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.) (“SEARLE”) is a Delaware corporation with its principal place of business in Illinois. In April 2000 SEARLE was acquired by PHARMACIA, and became a wholly-owned subsidiary of PHARMACIA. At the time of PFIZER’s acquisition of PHARMACIA, SEARLE was a wholly-owned subsidiary of PHARMACIA, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER. At all relevant times, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecoxib, under the trade name BEXTRA in Minnesota and throughout the United States. G.D. Searle LLC’s principal place of business is in Illinois and may be served through its registered agent at C T Corporation System, 208 South LaSalle Street, Suite 814, Chicago, Illinois 60604.

4. Defendant PHARMACIA is a Delaware corporation with its principal place of business in New Jersey. PHARMACIA was created in April 2000 through the merger of Pharmacia & Upjohn with Monsanto Company and its G.D. SEARLE unit. PHARMACIA is

now a wholly-owned subsidiary of PFIZER. At all relevant times, PHARMACIA, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecocixib, under the trade name BEXTRA in Minnesota and throughout the United States. Pharmacia's principal place of business is in Illinois and may be served at its principal place of business at 100 U. S. Highway 206 North, Peapack, New Jersey 07977.

5. Defendant MONSANTO COMPANY ("MONSANTO") was the parent corporation of SEARLE and is a Delaware corporation. At all times relevant hereto, MONSANTO, through its subsidiary companies, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product BEXTRA in Minnesota and throughout the United States. Defendant MONSANTO is licensed and registered to do business in the State of Minnesota and may be served through its registered agent at Monsanto Company, 380 Jackson Street #418, St. Paul, Minnesota 55101.

6. Valdecocixib was developed in 1998 by SEARLE and marketed jointly by SEARLE and PFIZER under the brand name BEXTRA. SEARLE was acquired by PHARMACIA, which was then acquired by PFIZER, in part so that PFIZER could take full control of BEXTRA.

7. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of BEXTRA, and advertised, promoted, marketed, sold and distributed BEXTRA as a safe prescription medication when, in fact, Defendants had reason to know, and did know, that BEXTRA was not safe for its intended purposes, for the patients for whom it was prescribed,

and for whom it was sold; and that BEXTRA caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

8. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants, or those Defendant's predecessors in interest.

9. Personal jurisdiction and subject matter jurisdiction are appropriate in this court as to all Defendants, as all Defendants have done business in Hennepin County, Minnesota, either directly or by agent, and have thus availed themselves of this jurisdiction.

10. The Defendants have been and/or are currently engaged in business, directly or by authorized agent, in Hennepin County, Minnesota. Venue and jurisdiction are therefore proper. The claims of the Plaintiff herein satisfy the jurisdictional amount of this Court.

Factual Background

A. Facts Regarding Plaintiff

11. Plaintiff was prescribed and began taking BEXTRA for the treatment of pain.

12. As a direct and proximate result of using BEXTRA, Plaintiff suffered a heart attack on or around July 11, 2004.

13. Plaintiff and Plaintiff's healthcare providers were at the time of Plaintiff's injuries unaware—and could not have reasonably known or have learned through reasonable diligence—that such injury directly resulted from Plaintiff's ingestion of BEXTRA and Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations.

14. Plaintiff used BEXTRA in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

15. Plaintiff would not have purchased and used BEXTRA had Defendants properly disclosed the risks associated with the drug, and through diligent effort was not able to discover the risk from BEXTRA prior to use of the drug.

A. Facts Regarding Bextra and Bextra's Market Launch

16. BEXTRA is one of a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil) are examples of well-known NSAIDs.

17. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

18. In addition to decreasing inflammation, the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

19. Prostaglandin I₂ is the predominant cyclooxygenase product in endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation, and preventing the proliferation of vascular smooth muscle. Whereas older NSAIDs inhibit Thromboxane A₂ and Prostaglandin I₂, the COX-2 inhibitors leave Thromboxane A₂ unaffected. Thromboxane A₂ is a potent platelet aggregator and vasoconstrictor, which is synthesized by platelets. Therefore, while the older NSAIDs suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors support it.

20. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood clots, rather they actually reduce the risk of clots and help protect heart function.

21. Defendants and other pharmaceutical companies set out to remedy these ulcer and bleeding problems suffered by some NSAID users by developing "selective" inhibitors that

would block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue while still reducing inflammation.

22. In making this decision, Defendants and their predecessors in interest either intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels and causes thromboxane A₂ to be uninhibited, causing blood clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke, unstable angina. The vasoconstriction and fluid retention cause the hypertension.

23. Pfizer launched Celebrex, the first of the three major COX-2 inhibitor drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and consumers of the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In May 1999, Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.

24. Seeking increased market share in this extremely lucrative market, Defendants, and their predecessors in interest, also sought approval of a “second generation” selective COX-2 inhibitor and filed for FDA approval of BEXTRA on January 16, 2001 for the (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

25. The FDA granted approval of the new drug on November 16, 2001, for two particular uses: (i) treatment of primary dysmenorrhea and (ii) relief for the signs and symptoms of osteoarthritis and rheumatoid arthritis.

26. The FDA did not grant approval to market and promote BEXTRA for the management or prevention of acute pain.

27. The FDA did not grant approval to promote BEXTRA as more effective than other NSAIDs in preventing clinically serious gastrointestinal events such as perforations, ulcers or gastric bleeding.

28. Even without a label that allowed Defendants to legitimately claim superior safety, when Defendants, and their predecessors-in-interest, began marketing BEXTRA in early 2002, Defendants and their representatives and agents misrepresented the safety profile of

BEXTRA to consumers, including Plaintiff, the medical community, healthcare providers, and third party payers. Defendants proceeded to promote, market, sell, and distribute BEXTRA as a much safer and more effective pain reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

B. Facts Regarding Bextra's Safety and Defendants' Knowledge Thereof.

29. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Defendants long before the FDA granted market approval in November 2, 2001. By 1997, and prior to the submission of the New Drug Application (the "NDA") for BEXTRA, Defendants was aware that, by inhibiting COX-2, BEXTRA altered the homeostatic balance between prostacyclin synthesis and thromboxane and thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, *Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, *JAMA*, August 22, 2001 at 954. Although all COX-2 inhibitors have this mechanism of action, BEXTRA was the most selective COX-2 inhibitor proposed for approval. Accordingly, it had the greatest potential to cause adverse cardiovascular and cerebrovascular events.

30. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania, reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that it was known as early as 1999 that selective COX-2 inhibitors, such as BEXTRA, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.

31. Nevertheless, on January 16, 2001, Defendants submitted an NDA to the FDA for BEXTRA, omitting information about the extent of the risks associated with BEXTRA. Without a complete picture of the potential hazards associated with the drug, the FDA approved BEXTRA on or about November 16, 2001.

32. Based on the studies performed on Celebrex, Vioxx, BEXTRA, and other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, Defendants knew when BEXTRA was being developed and tested that selective

COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors. Studies show that selective COX-2 inhibitors, including BEXTRA, decrease blood levels of a prostacyclin. When those levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

33. On December 9, 2004, the FDA issued new information on side effects associated with the use of BEXTRA and required the addition of certain warnings to, and the strengthening of other warnings on, the BEXTRA label. The enhanced warnings followed in the wake of the results of additional cardiovascular studies performed by Defendants, as well as numerous complaints to the FDA regarding severe skin reactions.

34. Yet well prior to this warning, Defendants had knowledge of the coronary and cardiovascular safety risks of BEXTRA from several studies. *See e.g., Otto, E.O., Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing Coronary Artery Bypass Surgery, The Journal of Thoracic and Cardiovascular Surgery*, June 2003 at 1481.

35. Even Defendants' own (and Pfizer funded) post- drug approval meta-analysis study (first presented on March 31, 2003 and again on May 15, 2003) included this data showing an increased cardiovascular risk in patients treated with BEXTRA after undergoing coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood clots in the legs and lungs. The results were particularly relevant and striking as each of the study participants who were a post-bypass surgery patient was taking anti-clotting agents at the time their exposure to BEXTRA was being tracked.

36. In mid-January 2005, a peer-reviewed paper from the University of Pennsylvania found that in patients having heart bypass surgery, those who took BEXTRA in the intravenous form, parecoxib, as opposed to a placebo, were three times more likely to have a heart attack or stroke.

37. From February 16-18, 2005, the FDA's Drug Safety and Risk Management Advisory Committee and the Arthritis Drug Advisory Committee met jointly to further examine the safety of COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham testified that selective COX-2 inhibitors increase the risk for adverse cardiovascular events at about the same rate as cigarette smoking, hypertension, and diabetes.

38. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of BEXTRA, Defendants failed to take any action to protect the health and welfare of patients, but instead, continued to promote the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

39. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily withdraw" BEXTRA from the U.S. market, stating:

"... the Agency has concluded that the overall risk versus benefit profile of BEXTRA is unfavorable. This conclusion is based on the potential increased risk for serious cardiovascular (CV) adverse events, which appears to be a class effect of non-steroidal anti-inflammatory drugs (NSAIDs) (excluding aspirin), an increased risk of serious skin reactions (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other NSAIDs, and the fact that BEXTRA has not been shown to offer any unique advantage over the other available NSAIDs."

40. FDA Alert for Healthcare Professionals, April 7, 2005. Continuing, the FDA noted:

"BEXTRA has been demonstrated to be associated with an increased risk of serious adverse CV events in two short-term trials in patients immediately post-operative from coronary artery bypass graft (CABG) surgery FDA has concluded that it is reasonable to extrapolate the adverse CV risk information for BEXTRA from the short-term CABG trials to chronic use given the fact that other COX-2 selective NSAIDs have been shown in long-term controlled clinical trials to be associated with an increased risk of serious adverse CV events (e.g., death, MI, stroke), and the well described risk of serious, and often life-threatening gastrointestinal bleeding To date, there have been no studies that demonstrate an advantage of BEXTRA over other

NSAIDs that might offset the concern about the[] serous skin risks, such as studies that show a GI safety benefit, better efficacy compared to other products, or efficacy in a setting of patients who are refractory to treatment with other products.”

41. The scientific data available during and after BEXTRA’s approval process made clear to Defendants that their formulation of BEXTRA would cause a higher risk of blood clots, stroke and/or myocardial infarctions among BEXTRA consumers, alerting them to the need to do additional and adequate safety studies.

42. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining Defendants’ failure to have conducted the necessary trials before marketing to humans “. . . it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events.”

43. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

44. Based upon readily available scientific data, Defendants knew, or should have known, that their pre-approval testing of BEXTRA did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take BEXTRA. Therefore, Defendants’ testing and studies were grossly inadequate. *See, e.g.*, PDR entry for BEXTRA (noting that: “**Platelets:** In four clinical studies with young and elderly (>=65 years) subjects, single and multiple doses up to 7 day mg BID had no effect on platelet aggregation”).

45. Had Defendants done adequate testing prior to approval and “market launch,” rather than the extremely short duration studies done on the small size patient base that was actually done) Pharmacia and Searle’s scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of BEXTRA consumers. Adequate testing would have shown that BEXTRA possessed serious side effects for individuals such as Plaintiff. Defendants should have taken appropriate measures to

ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

46. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but this information was intentionally suppressed by Defendants in order for them to gain significant profits from continued BEXTRA sales.

47. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

48. At the time Defendants manufactured, advertised, and distributed BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers such as Plaintiff would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAIDs.

C. Facts Regarding Defendants' Marketing and Sale of Bextra

49. Plaintiff and at all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers would perceive BEXTRA as a safer and better drug than its other NSAIDs and, therefore, purchase BEXTRA.

50. Defendants widely and successfully marketed BEXTRA throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff' prescribing physicians.

51. Despite knowledge of the dangers presented by BEXTRA, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for

the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, BEXTRA, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

52. In an elaborate and sophisticated manner, Defendants aggressively marketed BEXTRA directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payers, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include BEXTRA on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from Defendants' successful advertising and marketing blitz, third party payers were compelled to add BEXTRA to their formularies. Defendants' marketing campaign specifically targeted third party payers, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of BEXTRA.

53. Defendants represented that BEXTRA was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance, NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with long-term use. Defendants promoted BEXTRA as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

54. BEXTRA possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable

angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition, BEXTRA was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Defendants chose not to warn about these risks and dangers.

55. Defendants knew of these risks before the U.S. Food and Drug Administration (the “FDA”) approved BEXTRA for sale on November 16, 2001, but Defendants ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of BEXTRA. Defendants’ omission, suppression, and concealment of this important information enabled BEXTRA to be sold to, and purchased, or paid for by, the Consumers at a grossly inflated price.

56. Consequently, BEXTRA captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2002 alone (after a drug launch in March of 2002), sales of BEXTRA exceeded \$1.5 billion, despite the significantly higher cost of BEXTRA as compared to other pain relievers in the same family of drugs.

57. It was not until April 7, 2005, that Defendants finally acknowledged BEXTRA’s deleterious side effects and announced that they were withdrawing the drug from the worldwide market based on what it misleadingly termed “new” and “unexpected” evidence linking BEXTRA to an increased risk of heart attacks and strokes.

58. Had Defendants done adequate testing prior to approval and “market launch,” Pharmacia’s scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of BEXTRA consumers. Adequate testing would have shown that BEXTRA possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

59. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but this information was intentionally suppressed by Defendants in order for them to gain significant profits from continued BEXTRA sales.

60. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

61. At the time Defendants manufactured, advertising, and distributed BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers such as plaintiff would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAID drugs.

62. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers, including plaintiff, and their doctors would perceive BEXTRA as a better drug than its competitors and, therefore, purchase BEXTRA.

63. Defendants widely and successfully marketed BEXTRA throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff's prescribing physicians.

64. Prior to manufacturing, sale and distribution of BEXTRA, Defendants, through their officers, director and managing agents, had notice and knowledge from several sources, that BEXTRA presented substantial and unreasonable risks of harm to the consumer. As such, BEXTRA consumers, including Plaintiff, were unreasonably subject to risk of injury or death from the consumption of Defendants' product, BEXTRA.

65. Despite such knowledge, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, BEXTRA, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants and their officers, agents and managers intentionally proceeded with the inadequate testing, and then the manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence

66. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

67. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling BEXTRA. This duty included the duty not to introduce a pharmaceutical drug, such as BEXTRA, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

68. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiff and the Public of the risks, dangers and adverse side effects of their pharmaceutical drug BEXTRA.

69. Defendants breached their duties by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of BEXTRA, including:

(a) failing to use due care in the preparation and development of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

- (b) failing to use due care in the design of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- (c) failing to conduct adequate pre-clinical testing and research to determine the safety of BEXTRA;
- (d) failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of BEXTRA;
- (e) failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA;
- (f) failing to accompany BEXTRA with proper warnings regarding all possible adverse side effects associated with the use of BEXTRA;
- (g) failing to use due care in the manufacture, inspection, and labeling of BEXTRA to prevent the aforementioned risk of injuries to individuals who used BEXTRA;
- (h) failing to use due care in the promotion of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- (i) failing to use due care in the sale and marketing of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- (j) failing to use due care in the selling of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- (k) failing to provide adequate and accurate training and information to the sales representatives who sold BEXTRA;
- (l) failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of BEXTRA; and
- (m) being otherwise reckless, careless and/or negligent.

70. Despite the fact that Defendants knew or should have known that BEXTRA caused unreasonable and dangerous side effects which many users would be unable to remedy by

any means, Defendants continued to promote and market BEXTRA to consumers, including Plaintiff, when safer and more effective methods of pain relief were available.

71. Defendants were, or should have been had they exercised reasonable care, in possession of evidence demonstrating that BEXTRA caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of BEXTRA.

72. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described above.

73. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

74. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SECOND CLAIM FOR RELIEF
Strict Liability

75. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleged as follows:

76. At all times relevant to this action, Defendants were suppliers of BEXTRA, placing the drug into the stream of commerce. BEXTRA was expected to and did reach Plaintiff without substantial change in the condition in which it was manufactured and sold.

77. BEXTRA was unsafe for normal or reasonably anticipated use.

78. BEXTRA was defective in design or formulation because when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect. BEXTRA was also defective and unreasonably dangerous in that the foreseeable risk of injuries from BEXTRA exceeded the benefits associated with the design and/or formulation of the product.

79. BEXTRA is unreasonably dangerous: (a) in construction or composition; (b) in design; (c) because an adequate warning about the product was not provided; (d) because it does not conform to an express warranty of the manufacturer about the product.

80. BEXTRA as manufactured and supplied by Defendants was also defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study. Defendants failed to perform adequate testing before exposing Plaintiff to the medication, testing which would have shown that BEXTRA had the potential to cause serious side effects including the injuries suffered like the Plaintiff.

81. BEXTRA as manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from BEXTRA, they failed to provide adequate warnings to the medical community and the consumers, to whom they were directly marketing and

advertising BEXTRA; and, further, it continued to affirmatively promote BEXTRA as safe and effective.

82. BEXTRA was manufactured, distributed, tested, sold, marketed, advertised and promoted defectively by Defendants, and as a direct and proximate cause of Defendants' defective design of BEXTRA, Plaintiff used BEXTRA rather than other safer and cheaper NSAIDs. As a result, Plaintiff suffered the personal injuries described herein.

83. Information given by Defendants to the medical community and to the consumers concerning the safety and efficacy of BEXTRA, especially the information contained in the advertising and promotional materials, did not accurately reflect the potential side effects of BEXTRA.

84. Had adequate warnings and instructions been provided, Plaintiff would not have taken BEXTRA, and would not have been at risk of the harmful side effects described herein.

85. Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by BEXTRA.

86. Plaintiff could not, through the exercise of reasonable care, have discovered BEXTRA's defects or perceived the dangers posed by the drug.

87. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

88. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers,

including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

89. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF
Breach of Express Warranty

90. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

91. Defendants expressly represented to Plaintiff and other consumers and the medical community that BEXTRA was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

92. These warranties came in the form of:

- (a) Defendants' public written and verbal assurances of the safety and efficacy of BEXTRA;
- (b) Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for BEXTRA, which failed to warn of the risk of injuries inherent to the ingestion of BEXTRA, especially to the long-term ingestion of BEXTRA;
- (c) Verbal and written assurances made by Defendants regarding BEXTRA and downplaying the risk of injuries associated with the drug;
- (d) False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing BEXTRA during the period of Plaintiff's ingestion of BEXTRA, and;

(e) advertisements.

93. The documents referred to above were created by and at the direction of Defendants.

94. Defendants knew or had reason to know that BEXTRA did not conform to these express representations in that BEXTRA is neither as safe nor as effective as represented, and that BEXTRA produces serious adverse side effects.

95. BEXTRA did not and does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

96. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

97. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

98. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

99. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FOURTH CLAIM FOR RELIEF
Breach of Implied Warranty

100. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

101. Defendants manufactured, distributed, advertised, promoted, and sold BEXTRA.

102. At all relevant times, Defendants knew of the use for which BEXTRA was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

103. BEXTRA was not of merchantable quality and was not fit for its intended use, because it causes increased risk of serious cardiovascular and cerebrovascular adverse events, including heart attacks, strokes and other serious and harmful adverse health effects, such as death.

104. Defendants breached the implied warranty that BEXTRA was of merchantable quality and fit for such use.

105. Defendants were aware that consumers, including Plaintiff, would use BEXTRA for treatment of pain and inflammation and for other purposes.

106. Plaintiff and the medical community reasonably relied upon Defendants' judgment and expertise to only sell them or allow them to prescribe BEXTRA only if it was indeed of merchantable quality and safe and fit for its intended use. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for BEXTRA.

107. BEXTRA reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

108. Defendants breached their implied warranty to consumers, including Plaintiff; BEXTRA was not of merchantable quality or safe and fit for its intended use.

109. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

110. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

111. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF
Fraudulent Misrepresentation & Concealment

112. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

113. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers

of BEXTRA, and their intentional dissemination of promotional and marketing information about BEXTRA for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about BEXTRA's risks and harms to doctors and consumers.

114. Defendants made fraudulent affirmative misrepresentations with respect to BEXTRA in the following particulars:

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that BEXTRA had been tested and found to be safe and effective for the treatment of pain and inflammation; and

(b) Defendants represented that BEXTRA was safer than other alternative medications.

115. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of BEXTRA.

116. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that BEXTRA had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiff.

117. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of BEXTRA including, but not limited to, the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of BEXTRA in order to increase its sales.

118. The representations and concealment were undertaken by Defendants with an intent that doctors and patients, including Plaintiff, rely upon them.

119. Defendants' representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of BEXTRA.

120. Defendants' fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

121. Plaintiff's physicians and Plaintiff relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of BEXTRA in selecting BEXTRA treatment.

122. Plaintiff and the treating medical community did not know that the representations were false and were justified in relying upon Defendants' representations.

123. Had Plaintiff been aware of the increased risk of side effects associated with BEXTRA and the relative efficacy of BEXTRA compared with other readily available medications, Plaintiff would not have taken BEXTRA as she did.

124. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff sustained a heart attack; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

125. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

126. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

**SIXTH CLAIM FOR RELIEF
(Unjust Enrichment)**

127. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein.

128. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of BEXTRA.

129. Plaintiff paid for BEXTRA for the purpose of managing her pain safely and effectively.

130. Defendants have accepted payment from Plaintiff for the purchase of BEXTRA.

131. Plaintiff did not receive the safe and effective pharmaceutical product for which she paid.

132. It is inequitable and unjust for Defendants to retain this money because the Plaintiff did not in fact receive the product Defendant represented BEXTRA to be.

133. WHEREFORE, Plaintiff demands judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

1. General damages in excess of the jurisdictional amount of this Court;

2. Consequential damages;
3. Disgorgement of profits;
4. Restitution;
5. Punitive and exemplary damages;
6. Pre-judgment and post-judgment interest as provided by law;
7. Recovery of Plaintiff's costs including, but not limited to, discretionary


Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and

8. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

COMES NOW Plaintiff and demands a trial by jury on all issues presented herein.

Signed this 7 day of April, 2008.



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ATTORNEYS FOR PLAINTIFF

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

SARAH BENTON,

Case No.: 08-CV- 00954-JRT/FLN

Plaintiff,

v.

**PFIZER, INC., PHARMACIA
CORPORATION, G.D. SEARLE LLC,
and MONSANTO COMPANY,**

**DEFENDANTS PFIZER INC.,
PHARMACIA CORPORATION,
AND G.D. SEARLE LLC'S ANSWER
TO PLAINTIFF'S COMPLAINT**

Defendants.

Jury Trial Demanded

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company¹) ("Pharmacia") and G.D. Searle LLC ("Searle") (collectively "Defendants") and file this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

**I.
PRELIMINARY STATEMENT**

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra®.

¹ Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed Bextra®. Given that Plaintiff alleges in the Complaint that Monsanto Company was involved in distributing Bextra®, *see* PLAINTIFF'S COMPLAINT at ¶ 5, Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

II.
ORIGINAL ANSWER

Response to Allegations Regarding Parties

1. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny that Plaintiff is entitled to any relief or damages. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age or citizenship, and, therefore, deny the same. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

2. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York, and that it is registered to do business in the State of Minnesota. Defendants admit that Pfizer may be served through its registered agent. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois, and that it is registered to do business in the State of Minnesota. Defendants admit that Searle may be served through its registered agent. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever manufactured, marketed, sold, or distributed Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia.

As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or distributed Bextra®, Defendants therefore state that the 2000 Monsanto is not a proper party in this matter. Defendants deny the remaining allegations in this paragraph of the Complaint. Defendants state that the response to this paragraph of the Complaint regarding Monsanto is incorporated by reference into Defendants' responses to each and every paragraph of the Complaint referring to Monsanto and/or Defendants.

6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

7. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

8. Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are therefore without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

9. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants deny the remaining allegations in this paragraph of the Complaint.

10. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants are without knowledge sufficient to form a belief as to the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims the amount in controversy satisfies the jurisdictional amount of this Court. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Factual Allegations

11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s medical condition or whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s medical condition or whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and

effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that, in the ordinary case, Bextra® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen and ibuprofen are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding aspirin, naproxen and ibuprofen. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such

allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

17. The allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

18. The allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

19. The allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

20. The allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

21. Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

22. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a

belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless, Defendants admit that Celebrex® was launched in the United States in February 1999. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

24. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

25. Defendants admit that Bextra® was approved by the FDA on November 16, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

26. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

27. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when

used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

30. The allegations in this paragraph of the Complaint are not directed towards Defendants, and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this paragraph of the Complaint.

32. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

33. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to

characterize the Talk Paper is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

34. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Plaintiff fails to provide the proper context for the allegations concerning the “post-drug approval meta-analysis study” in this paragraph of the Complaint. Defendants are without sufficient information to confirm or deny such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

36. The allegations in this paragraph of the Complaint are not directed towards Defendants, and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. The allegations in this paragraph of the Complaint are not directed towards Defendants, and, therefore, no response is necessary. Should a response be deemed necessary, Defendants admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee was held on February 16-18, 2005. Defendants state that the referenced testimony speaks for itself and respectfully refer the Court to the testimony for its actual language and text. Any attempt to characterize the testimony is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

42. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

43. The allegations in this paragraph of the Complaint are not directed towards Defendants, and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

44. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

45. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

47. Defendants deny the allegations in this paragraph of the Complaint.

48. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the allegations in this paragraph of the Complaint.

49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

51. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

52. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

54. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

56. Defendants deny the allegations in this paragraph of the Complaint.

57. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market as of April 7, 2005. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

58. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

59. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

60. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

61. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

62. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

63. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit, as indicated in the package

insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

64. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

65. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Negligence

66. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

67. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required,

Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

70. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that

Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

72. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

73. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 74 of the Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

75. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

76. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

77. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

78. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

79. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

80. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

81. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-

approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

84. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

85. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

86. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

87. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

88. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Breach of Express Warranty

90. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

91. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

92. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved

prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint, including all subparts.

93. Defendants deny the allegations in this paragraph of the Complaint.

94. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

95. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct the remaining allegations in this paragraph of the Complaint.

96. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

97. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

98. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

99. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Implied Warranty

100. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

101. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

102. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

103. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

104. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

105. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms

of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

106. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

107. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

108. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

109. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

110. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

111. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment

112. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

113. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

114. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

115. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

116. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

117. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

118. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

119. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

120. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

121. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and

effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

122. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

123. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

124. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

125. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

126. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Unjust Enrichment

127. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

128. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants

admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

129. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

130. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

131. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

132. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,” Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

III.
GENERAL DENIAL

Defendants deny the allegations and/or legal conclusions set forth in Plaintiff’s Complaint that have not been previously admitted, denied, or explained.

IV.
AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants’ labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff’s causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or persons acting on its behalf after the product left the control of Defendants.

Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, Article I, § 17 of the Constitution of the States of Minnesota, and the Constitution of the State

of Georgia, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Minnesota and Georgia law, including, but not limited to, Minn. Stat. § 549.191 (2006).

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Minnesota and Georgia. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Plaintiff's claim for punitive damages is barred pursuant to Minn. Stat. § 549.191.

Fifty-sixth Defense

56. Defendants avail themselves of all of the provisions, defenses, and standards of proof in O.C.G.A. § 51-12-5.1 concerning punitive damages.

Fifty-seventh Defense

57. Plaintiff's claims for strict liability are barred as to Defendants inasmuch as Defendants are not manufacturers of the drug Bextra® within the meaning of O.C.G.A. § 51-1-11(b)(1) and applicable Georgia law.

Fifty-eighth Defense

58. Plaintiff's claims for fraud and misrepresentation(s) are barred and should be dismissed because they have not been pled with sufficient particularity to meet the requirements of O.C.G.A. § 9-11-9(b).

Fifty-ninth Defense

59. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

**V.
JURY DEMAND**

Defendants hereby demand a trial by jury.

**VI.
PRAYER**

WHEREFORE, Defendants pray that Plaintiff take nothing by this suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which Defendants may be justly entitled.

Dated: April 30, 2008

FAEGRE & BENSON LLP

s/ Joseph M. Price

Joseph M. Price, # 88201

Erin M. Verneris # 0335174

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*Attorneys for Defendants Pfizer Inc.,
Pharmacia Corporation, and G.D. Searle LLC*

Inasmuch as no objection is pending at this time, the stay is lifted.

MAY 20 2008

CLERK'S OFFICE
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

MAY - 2 2008

FILED
CLERK'S OFFICE

IN RE: BEXTRA AND CELEBREX MARKETING, SALES
PRACTICES AND PRODUCTS LIABILITY LITIGATION

MDL No. 1699

FILED

(SEE ATTACHED SCHEDULE)

MAY 20 2008

CONDITIONAL TRANSFER ORDER (CTO-102)

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

On September 6, 2005, the Panel transferred 30 civil actions to the United States District Court for the Northern District of California for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 391 F.Supp.2d 1377 (J.P.M.L. 2005). Since that time, 1,214 additional actions have been transferred to the Northern District of California. With the consent of that court, all such actions have been assigned to the Honorable Charles R. Breyer.

It appears that the actions on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Northern District of California and assigned to Judge Breyer.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the Northern District of California for the reasons stated in the order of September 6, 2005, and, with the consent of that court, assigned to the Honorable Charles R. Breyer.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Northern District of California. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

A CERTIFIED TRUE COPY

MAY 20 2008

ATTEST
FOR THE JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

SCANNED

MAY 22 2008

U.S. DISTRICT COURT, N.D. CALIF.

I hereby certify that the annexed instrument is a true and correct copy of the original on file in my office.
ATTEST:

RICHARD W. WIEKING
Clerk, U.S. District Court
Northern District of California
By Simone Volk
Deputy Clerk

Date 5-20-08

**IN RE: BEXTRA AND CELEBREX MARKETING, SALES
PRACTICES AND PRODUCTS LIABILITY LITIGATION**

MDL No. 1699

SCHEDULE CTO-102 - TAG-ALONG ACTIONS

DIST. DIV. C.A. #

CASE CAPTION

KANSAS

KS 2 07-2457

Valerie Coats v. Pfizer Inc.

MINNESOTA

MN 0 08-950

Joanne Schwandt v. Pfizer Inc., et al.

MN 0 08-954

Sarah Benton v. Pfizer Inc., et al.

NEW YORK SOUTHERN

NYS 1 08-2889

Paulette Johnson v. Pfizer Inc.

NYS 1 08-2890

Linda Marler, et al. v. Pfizer Inc.

NYS 1 08-3353

Betty Sundhausen, et al. v. Pfizer Inc.

NYS 1 08-3394

Marie Maki v. Pfizer Inc.

NYS 1 08-3395

Jimmie L. Brockman v. Pfizer Inc.

**IN RE: BEXTRA AND CELEBREX MARKETING, SALES
PRACTICES AND PRODUCTS LIABILITY LITIGATION**

MDL No. 1699

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OFFICE OF THE CLERK
UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Richard W. Wieking
Clerk

450 Golden Gate Avenue
San Francisco, CA 94102
415.522.2000

May 20th, 2008

District of Minnesota
300 South Fourth Street
Minneapolis, MN 55415

Re: MDL 05-1699 In re Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation

Title of Case(s)
Sarah Benton v. Pfizer Inc., et al.

Your Case Number(s)
C.A. No. 08-954

Dear Clerk:

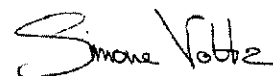
Enclosed is a certified copy of ~~the~~ order from the Judicial panel on Multidistrict Litigation transferring the above entitled action to the Northern District of California, San Francisco Division. The case has been assigned to the Honorable Charles R. Breyer for coordinated or consolidated pretrial processing pursuant to 28 USC §1407.

Please forward the **original record** and a **certified copy of the docket entries** in the case listed above along with the enclosed copy of this transmittal letter to:

United States District Court
Northern District of California
450 Golden Gate Avenue, P.O. Box 36060
San Francisco, CA 94102
Attn: Simone Voltz

If the case is an electronic case filing please do one of the following: 1) e-mail the PDF documents, as separate PDF files, including a PDF copy of the docket sheet to SFmdl_clerk@cand.uscourts.gov, 2) provide us with a temporary log in and a password to directly access your database and to expedite the downloading of the PDF files we need and/or require, or, 3) if you prefer, on a disc. We appreciate your prompt attention to this matter.

Sincerely yours,
Richard W. Wieking, Clerk



By: Simone Voltz
Deputy Clerk

Encl.

**UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION**

CHAIRMAN:
Judge John G. Heyburn II
United States District Court
Western District of Kentucky

MEMBERS:
Judge D. Lowell Jensen
United States District Court
Northern District of California

Judge J. Frederick Motz
United States District Court
District of Maryland

Judge Robert L. Miller, Jr.
United States District Court
Northern District of Indiana

Judge Kathryn H. Vratil
United States District Court
District of Kansas

Judge David R. Hansen
United States Court of Appeals
Eighth Circuit

Judge Anthony J. Scirica
United States Court of Appeals
Third Circuit

DIRECT REPLY TO:

Jeffery N. Lüthi
Clerk of the Panel
One Columbus Circle, NE
Thurgood Marshall Federal
Judiciary Building
Room G-255, North Lobby
Washington, D.C. 20002

Telephone: (202) 502-2800
Fax: (202) 502-2888
<http://www.jpml.uscourts.gov>

May 20, 2008

Richard W. Wieking, Clerk
Phillip Burton U.S. Courthouse
Box 36060
450 Golden Gate Avenue
San Francisco, CA 94102-3489

Re: MDL No. 1699 -- IN RE: Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation

(See Attached CTO-102)

Dear Mr. Wieking:

I am enclosing a certified copy and one additional copy of a conditional transfer order filed by the Panel in the above-captioned matter on May 2, 2008. As stipulated in Rule 7.4(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), transmittal of the order has been stayed 15 days to give any party an opportunity to oppose the transfer. The 15-day period has now elapsed, no opposition was received, and the order is directed to you for filing.

The Panel's governing statute, 28 U.S.C. §1407, requires that the transferee clerk "...transmit a certified copy of the Panel's order to transfer to the clerk of the district court from which the action is being transferred."

A list of involved counsel is attached.

Very truly,

Jeffery N. Lüthi
Clerk of the Panel

By Dana R. Stewart
Deputy Clerk

Attachment

cc: Transferee Judge: Judge Charles R. Breyer
Transferor Judges: Judge Carlos Murguia; Judge John R. Tunheim; Judge Robert W. Sweet
Transferor Clerks: Timothy M. O'Brien; Richard Sletten; J. Michael McMahon

JPML Form 36

CLOSED, CV, JRTLC2

**U.S. District Court
District of Minnesota (DMN)
CIVIL DOCKET FOR CASE #: 0:08-cv-00954-JRT-FLN
Internal Use Only**

Benton v. Pfizer, Inc. et al **DO NOT DOCKET. CASE HAS
BEEN TRANSFERRED OUT.**

Assigned to: Judge John R. Tunheim

Referred to: Magistrate Judge Franklin L. Noel

Cause: 28:1332-pip-Diversity-Personal Injury, Product
Liability

Date Filed: 04/04/2008

Jury Demand: Plaintiff

Nature of Suit: 365 Personal Inj. Prod.
Liability

Jurisdiction: Diversity

Plaintiff

Sarah Benton

represented by **Ted G Meadows**

Beasley Allen Crow Methvin Portis &
Miles, PC

PO Box 4160

Montgomery, AL 36103-4160

334-269-2343

Fax: 334-954-7555

Email: ted.meadows@beasleyallen.com

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

V.

Defendant

Pfizer, Inc.

represented by **Joseph M Price**

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90 S 7th St Ste 2200

Mpls, MN 55402-3901

612-766-7000

Fax: 612-766-1600

Email: jprice@faegre.com

LEAD ATTORNEY

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Defendant

Pharmacia Corporation

represented by **Joseph M Price**

(See above for address)

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Defendant

G. D. Searle LLC
formerly known as
 G.D. Searle & Co.

represented by **Joseph M Price**
 (See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

Monsanto Company

Date Filed	#	Docket Text
04/04/2008	<u>1</u>	COMPLAINT against Pfizer, Inc., Pharmacia Corporation, G. D. Searle LLC, Monsanto Company (Filing fee \$ 350 receipt number 4022404.) assigned to Judge John R. Tunheim per Master list and referred to Magistrate Judge Franklin L. Noel, filed by Sarah Benton. (Attachments: # <u>1</u> Civil Cover Sheet) (RJL) (Entered: 04/04/2008)
04/04/2008		Summons Issued as to Pfizer, Inc., Pharmacia Corporation, G. D. Searle LLC, Monsanto Company. (RJL) (Entered: 04/04/2008)
04/04/2008		(Court only) *** Copy of complaint sent to the MDL Panel. (RJL) (Entered: 04/04/2008)
04/30/2008	<u>2</u>	ANSWER to Complaint by Pfizer, Inc., Pharmacia Corporation, G. D. Searle LLC. (Price, Joseph) (Entered: 04/30/2008)
04/30/2008	<u>3</u>	RULE 7.1 DISCLOSURE STATEMENT by Pfizer, Inc., Pharmacia Corporation, G. D. Searle LLC that there is no such parent or publicly held corporation to report. (Price, Joseph) (Entered: 04/30/2008)
04/30/2008	<u>4</u>	CERTIFICATE OF SERVICE by Pfizer, Inc., Pharmacia Corporation, G. D. Searle LLC re <u>2</u> Answer to Complaint, <u>3</u> Rule 7.1 - Disclosure Statement (Price, Joseph) (Entered: 04/30/2008)
05/22/2008	<u>5</u>	CERTIFIED COPY OF CONDITIONAL TRANSFER ORDER (CTO-102), transferring case to the Northern District of California per MDL Panel for coordinated or consolidated pretrial proceedings. Case assigned to Judge Charles R. Breyer. (akl) (Entered: 05/22/2008)
05/22/2008		NOTICE to Attorney: Emailed case to the Northern District of California (akl) (Entered: 05/22/2008)